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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/791,283	03/03/2004	Birke Bartosch	P08199US00/BAS	9764
881	7590	09/06/2005	EXAMINER	
STITES & HARBISON PLLC 1199 NORTH FAIRFAX STREET SUITE 900 ALEXANDRIA, VA 22314			CHEN, STACY BROWN	
			ART UNIT	PAPER NUMBER
			1648	

DATE MAILED: 09/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/791,283

Applicant(s)

BARTOSCH ET AL.

Examiner

Stacy B. Chen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 July 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) 9 and 10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>6/28/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's election of Group I, claims 1-8 in the reply filed on July 18, 2005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). With regard to the subject matter of claim 9-10, classified in class 435, subclass 5, now amended to recite methods of vaccination, this invention is separate and distinct from Group I, claims 1-8. Methods of vaccination and methods of producing virus particles are not the same. The methods are accomplished with different steps. While one of the reagents is the same, the manner in which the reagent is used is completely different in each invention. Therefore, claims 1-8 are under examination, while claims 9-10 are withdrawn from consideration.

Oath/Declaration

2. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

It does not identify the city and either state or foreign country of residence of each inventor. The residence information may be provided on either on an application data sheet or supplemental oath or declaration.

In this case, the full address of the first-named inventor is incomplete, listing only a street address, but not the city or country.

Claim Objections

3. Claims 1-8 are objected to for failing to spell out acronyms at their first occurrence.

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Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Claim 2 recites improper Markush group language. Proper language is, “selected from the group consisting of...and...” Correction is required to overcome this rejection.
- Claims 1-8 recite “derived”, which does not clearly set forth what elements are retained from the source retrovirus or pestivirus. It is suggested that Applicant delete all “derived” language to overcome this rejection. Lacking a clear definition of these terms, one cannot determine the metes and bounds of the claims.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marasco *et al.*

(WO 00/55335 A1, “Marasco”. In view of Schlapp *et al.* (EP 1170367 A1, “Schlapp”) The

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claims are drawn to a method for producing pestivirus-like particles ex vivo comprising the steps of:

- Providing a first nucleic acid sequence comprising a packaging competent retroviral-derived genome
- Providing a second nucleic acid sequence comprising a cDNA encoding core proteins from said retrovirus
- Providing a third nucleic acid sequence comprising a cDNA encoding a polyprotein comprising successively a pestivirus core protein, and a E^{ms} protein and/or pestivirus E1 protein and/or a pestivirus E2 protein, and optionally a pestivirus p7 protein
- Transfecting host cells with said nucleic acid sequences and maintaining the transfected cells in culture for sufficient time to allow expression of the cDNAs to produce structural proteins from pestivirus and retrovirus; and allowing the structural proteins to form virus-like particles.

Specifically, the core proteins are from a retrovirus selected from the group consisting of MLV, ALV, RSV, MPMV, HIV-1, HIV-2, SIV, EIAV, CAEV and HFV. The E^{ms}, E1 and E2 pestivirus proteins, and optionally p7 pestivirus protein are from the same pestivirus. The pestivirus is BCDV, SFV or BDV. Also claimed are the virus particles produced from the methods.

Marasco teaches pseudotyped lentiviral vectors comprising:

- A first vector containing a lentiviral gag gene (core)
- A second vector containing an env gene (gp41/120)

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- A lentiviral pol gene (reverse transcriptase) encoding a lentiviral pol protein on the first or second vectors, and
- A packaging vector containing a nucleic acid sequence encoding a desired molecule.

The env gene can be heterologous to the lentiviral pol protein, selected from a variety of viral sources, including pestiviruses among others (Marasco, claims 1-3). Lentiviruses include FIV, ELAV and HIV, for example (Marasco, claims 7-17). Marasco is silent on the use of pestivirus core and E^{ms} protein. (Note that the instant claims do not require E1, E2 or p7.) However, Schlapp teaches BVDV virus-like particles comprising a BHV-1 genome backbone with BVDV (a pestivirus) proteins including N (core protein packages viral RNA to form the nucleocapsid, N protein), E^{ms}, E1 and E2 (Schlapp, page 3, lines 9-25).

It would have been obvious to use the core and E^{ms} genes as the env gene of Marasco's method. One would have been motivated to use core and E^{ms} because Marasco teaches that pestivirus env proteins are useful in the invention (Marasco, page 6, second full paragraph, and claim 3). One would have had a reasonable expectation of success that the E^{ms} and core proteins would have been functional in Marasco's vector system because core is a structural protein that forms the nucleocapsid and is antigenic. The E^{ms} protein is part of the envelope that is also antigenic, thus functioning in the same manner as Marasco's suggested pestivirus envelope protein. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

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evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Conclusion

6. No claim is allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James C. Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.



Stacy B. Chen
August 23, 2005